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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/558,155

01/03/2007

Takaji Wakita

1254-0299PUS1

6809

2292 7590 04/30/2010  
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EXAMINER

SCHULTZ, JAMES

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

04/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/558,155	<b>Applicant(s)</b> WAKITA ET AL.	
	<b>Examiner</b> JD SCHULTZ	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-9, 21 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See action</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed February 1, 2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed July 16, 2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

This application contains claims 4 and 14-20, and claim language drawn SEQ ID NOS: 2, 10, and 12, directed to inventions nonelected with traverse in the reply filed on August 11, 2008. A complete reply to the instant rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on December 3, 2009 was filed before the mailing date of the instant action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner, and a signed and initialed copy is enclosed herewith.

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***Claim Objections***

Claims 1, and 3 are objected to because of the following informalities:

Claim 1 is representative of claim 3, and recites: “A replicon RNA...containing at least the 5' untranslated region, the nucleotide sequence encoding NS3 protein, NS4A protein, NS4B protein, NS5A protein and NS5B protein and the 3' untranslated region on the genomic RNA of JFH-1 strain of hepatitis C virus of genotype 2a. It would appear that the word “on” should be changed to “from”.

***Claim Rejections - 35 USC § 103***

All rejections under 35 U.S.C. § 103(a) are considered to have been overcome in view of the uncertainty in making HCV-2a replicons, particularly since no evidence has been found that any such HCV-2 replicons were ever made prior to the instant disclosure, and considering statements in the art that suggest that previous attempts to develop replicons for other HCV genotypes had been largely unsuccessful.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claims 1-3, 5-9, 21 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Date et al. (Kato, Takanobu [Reprint Author]; Date, Tomoko; Miyamoto, Michiko; Wakita, Takaji; Hepatology, (October 2003) Vol. 38, No. 4 Suppl 1, pp. 469A).

Kato teaches a replicon isolated from the JFH-1 HCV strain. Kato teaches that this construct was replicated in Huh7 cells, using selection markers. Although Kato does not teach any sequences per se, it is referred to in the prior art in the same manner that it is referred to in the instant application (i.e. the JFH-1 strain). SEQ ID NOS: 1, 3, 9 and 11 are therefore presumed to correspond to the replicon taught in the prior art absent evidence to the contrary. Since foreign priority has been claimed but no certified translation has been provided, such a translation may properly antedate this reference.

Claim 21 is included in this rejection. The claim language recites “A replicon RNA, comprising a nucleotide sequence derived from the nucleotide sequence as set forth in SEQ ID NO: 1 by at least one mutation selected from the group consisting of ....” The claim language “a nucleotide sequence” is considered to be permissive language that allows for art to be cited that merely teaches fragments or derivatives of SEQ ID NO: 1, which it is maintained that the instantly cited art does. It is not maintained that the cited art teaches the claimed mutations, rather it is considered to teach “a” nucleotide sequence (i.e. any fragment of SEQ ID NO: 1) that has been derived from the mutated SEQ ID NO: 1. This is particularly true since the phrase “...by at least one...” does not appear to clearly refer back to a difference as suggested by the rest of the claim. Amendment to remove the permissive language and have the “...by at least one...” phrase would likely be remedial depending on how its worded.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JD SCHULTZ whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JD SCHULTZ/  
Primary Examiner, Art Unit 1633